					Patent and Trade Office; U.S DEPARTMENT OF COMMERCE	
	Substitute for form 1449A	/PTO		COMPLETE KNOWN		
	INFORMATION DISCLOSURE		Application Number	10/010,345		
	STATEMENT BY APPLICANT		Filing Date	December 5, 2001		
\o\	STATEMENT BY APPLICANT		First Named Inventor	A.G. Daifotis		
	ליבי מומר ל	•	,	Group Art Unit	1617	
AU6	se as many	sheets as n	ecessary)	Examiner Name	T.J. Criares	
SEAT &	Shorte 1	of	3	Attorney Docket Number	20002YIBCA	

			U.S. PATEN	IT DOCUMENTS	_
Examiner Initials*	Cite No.	U.S. Patent Docur		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
P	w	6,225,294			
					~D.
HOTE HOTE		71		7	
	AUu				
	, #2				THE BOY OF THE PARTY OF THE PAR
	-				
ع. چ د	***				8

		ĺ	Foreign Patent Docume		T DOCUMENTS	Date of Publication of Cited Document MM-DD-YYYY	
Examiner Initials*	Cite No.	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document		
W	M	F	IU P9602888		Merck & Co., Inc.	03/28/1997	
	N	F	HU P9403762		Procter & Gamble Pharm., Inc.	09/28/1995	
	0	V	VO 96/38156		Merck & Co., Inc.	12/05/1996	
1	P	E	EP 0 128 736 A1		Yamanouchi Pharm. Co. Ltd.	12/19/1984	
					,		

Examiner Signature

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

		• -			Patent and Trad				
1		Substitute for form 1449A/PTO			COMPLETE KNOWN				
7		INFORMATION I	DIS	CLOSURE '	Application Number	10/010,345			
/0	۲ ۳ ۶	COM DURA ATERITO DAY	A TO	DI ICANT	Filing Date	December 5, 2001			
/		STATEMENT BY	Ar	PLICANI	First Named Inventor	A.G. Daifotis			
AUG (Z.				,	Group Art Unit	1617			
EREC.	RADEM	sse as many sheets	as n	necessary)	Examiner Name	T.J. Criares			
Ţ	Sheet	_	of	3	Attorney Docket Number	20002YIBCA			

		OTHER NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
M	CI	Men's Osteoporosis Support Group, Vol. 1, Issue 2, 1 July 1997
	CJ	Rote List 1997, 66 023 (Fosamax)
	СК	Reddy M.S. et al, J. Periodontol, 1995, Vol. 66(3), pp. 211-217, "Alendronate Treatment of Naturally-Occurring Periodontitis in Beagle Dogs".
	CL	Fleisch H., "Bisphosphonates in Bone Disesase from the Laboratory to the patient", 1995 (Book)
	СМ	Black D.M. et al., The Lancet, 1996, 348, pp. 1535-1541, "Randomised trial of effect of alendronate on risk of fracture in women with existing vertebral fractures".
	CN	Affidavit of Gideon Rodan from validity trial of IL 94612 dated 17 Nov. 2000
	со	Merck & Co., Inc Instructions for Once Weekly Fosamax, January 2001
	СР	Lombardi et al., Ann. Ital. Med. Int. 7, 1992, 3 Suppl., pp. 158-165, "Clinical trials with bisphosphonates"
	CQ	Reid et al, American Journal of Medicine, 1996, Vol. 101, pp. 341-348, "Biochemical and Radiologic Improvement in Paget's Disease of Bone Treated with Alendronate: A Randomized, Placebo-controlled Trial".
	CR	Passeri et al, Bone and Mineral, 1991, Vol. 15, pp. 237-248, "Intermittent treatment with intravenous 4-amino-1-hydroxybutylidene-1,1-bisphosphonate (AHBuBP) in the therapy of postmenopausal osteoporosis".
	CS	Devogelaer et al, Bone, 1996, Vol. 18(2), pp. 141-150, "Oral Alendronate Induces Progressive Increases in Bone Mass of the Spine, Hip, and Total Body Over 3 Years in Postmenopausal Women with Osteoporosis".
	СТ	Siris et al, J. Clin. Endo. Metab., 1996, Vol. 81(3), pp. 961-967, "Comparative Study of Alendronate Versus Etidronate for the Treatment of Paget's Disease of Bone".
4	CU	Toolan et al, J. Bone Min. Res., 1992, Vol. 3, pp. 1399-1406, "Effects of 4-Amino-1-Hydroxybutylidene Bisphosphonate on Bone Biomechanics in Rats".
	CV	Balena et al, Bone, 1993, Vol. 14, pp. 499-504, "the Aminobisphosphonate Alendronate Inhibits Bone Loss Induced by Thyroid Hormone in the Rat Comparison Between Effects on Tibiae and Vertebrae".
V	CW	Liberman et al., The New England Journal of Medicine, Vol. 333(22), 1995, p. 1437, "Effect of Oral Alendronate on Bone Mineral Density and the Incidence of Fractures in Postmenopausal Osteoporosis".

Examiner Signature	1/6	Date Considered	6/25/04

	•					Patent and Trad
	Substitute t	or form 1449A/PTO	_			COMPLETE KNOWN
			DIS	CLOSURE '	Application Number	10/010,345
	THE ATT	INAZIRAZION INAZ	7 A D	DIICANT	Filing Date	December 5, 2001
	81A1	the as many sheets as necessary)	PLICANI	First Named Inventor	A.G. Daifotis	
AUG			,	Group Art Unit	1617	
PERE		e as many sheets	s as n	ecessary)	Examiner Name	T.J. Criares
4	RADEMAN	3	of	3	Attorney Docket Number	20002YIBCA

	OTHER NON PATENT LITERATURE DOCUMENTS		
			Examiner Initials*
es:	CX Fleisch et al, Hormone and Metabolic Research, Vol. 29 (1997), pp. 145-150, "In Mechanisms of Action and Clinical Use in Osteoporosis - An Update".	CX	pr
	CY E-mail communication of February 20, 1998 from Melton to DiCesare et al.	CY	1
/		•••	·
Plio H			
E TOWN			
CHO CHO			

Date Considered Examiner Signature